MAR 2 9 2002

K020702

510 (K) Summary

1. **Submitter's Name and Address**
   Ann-Marie O'Keefe
   Canadian Theatre Products Ltd.
   #210-828 Harbourside Drive
   North Vancouver, BC
   Canada, V7P 3R9
   Prepared on: February 20,2002

2. **Contact Person**
   Ann-Marie O'Keefe
   Sales Co-ordinator
   Tel: (604) 904-9577
   Fax: (604) 904-9588

3. **Device Name:**
   Proprietary Name: O'Regan Disposable Anoscope
   Common Name: Disposable Anoscope
   Classification Name: Class II

4. **Predicate Device**
   Company Name: Dispos-A-Scope
   Proprietor Name: Dispos-A-Scope
   Common Name: Disposable Anoscope
   510 (K) Number: K993738

- **Device Description**: Similar to device's marketed prior to or after May 28,1976

- **Intended Use:** The O'Regan Disposable Anoscope is intended for physician use to examine the anal sphincter and anus, and, using additional accessories, to perform various diagnostic and therapeutic procedures.

  The O'Regan Disposable Anoscope is identical to other legal marketed devices such as the Dispos-A-Scope in terms of material, disposability, non-powered, design, and usage.

- The O'Regan Disposable Anoscope is constructed from a Medical Grade-Atohass Medical SG&101PH material, and is FDA certified.

- The O'Regan Disposable Anoscope is for single patient use only, thus disposable eliminating the risk of cross infection and nullifying the need for sterilization.

- The O'Regan Disposable Anoscope is non-powered. It does not conduct electricity and is non-thermogenic.

- The O'Regan Disposable Anoscope has a distal and proximal port enabling precise isolation and accuracy of tissue or pathology.

- The O'Regan Disposable Anoscope has an ergonomic handle facilitating accurate physician manipulation.

- The O'Regan Disposable Anoscope will not crack or craze during normal one time usage.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Ann-Marie O'Keefe
Sales Co-ordinator
Canadian Theatre Products Ltd.
Suite #210 – 828 Harbourside Drive
North Vancouver, BC
CANADA, V7P 3R9

Re: K020702
Trade/Device Name: O'Regan Disposable Anoscope
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: 78 FER
Dated: February 20, 2002
Received: March 4, 2002

Dear Ms. O'Keefe:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indication for Use Statement

510 (k) Number: Pending K020702

Device Name: O'Regan Disposable Anoscope

Indication for use:

- The O'Regan Disposable Anoscope is intended for physician use to examine the anal sphincter and anus, and, using additional accessories, to perform various diagnostic and therapeutic procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHR PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over The Counter Use__
(Per 21 CFR 801.109) (Optional Format 1-2-96)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K020702